

DOCKET NO.: 284468US0PCT



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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

IN RE APPLICATION OF:

Fujio MIZUKAMI, et al.

SERIAL NO: 10/563,870

GROUP: 1652

FILED: January 9, 2006

EXAMINER:

FOR: PROTEIN-REFOLDING MATERIAL

**LETTER**

Mail Stop DD  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith are an International Preliminary Report on Patentability and Written Opinion for the Examiner's consideration. The Reference(s) cited therein have been previously filed on April 6, 2006.

Respectfully Submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.  
Norman F. Oblon

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From the INTERNATIONAL BUREAU

**PCT**

NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY  
(CHAPTER I OR CHAPTER II  
OF THE PATENT COOPERATION TREATY)  
(PCT Rules 44bis.3(c) and 72.2)

To:

SUDO, Masahiko  
Shinyo Bldg. 6F  
6-1, Nihonbashi-Muromachi 1-chome  
Chuo-ku, Tokyo 103002  
JAPON

Date of mailing ( <i>day/month/year</i> ) 26 May 2006 (26.05.2006)	
Applicant's or agent's file reference 200407F-0411	<b>IMPORTANT NOTIFICATION</b>
International application No. PCT/JP2004/009664	International filing date ( <i>day/month/year</i> ) 07 July 2004 (07.07.2004)
Applicant NATIONAL INSTITUTE OF ADVANCED INDUSTRIAL SCIENCE AND TECHNOLOGY et al	

**1. Transmittal of the translation to the applicant.**

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

**2. Transmittal of the copy of the translation to the designated or elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

**3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. +41 22 740 14 35	Authorized officer  Masashi Honda  Facsimile No. +41 22 338 70 10
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# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 200407F-0411	<b>FOR FURTHER ACTION</b>	See item 4 below
International application No. PCT/JP2004/009664	International filing date ( <i>day/month/year</i> ) 07 July 2004 (07.07.2004)	Priority date ( <i>day/month/year</i> ) 09 July 2003 (09.07.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant NATIONAL INSTITUTE OF ADVANCED INDUSTRIAL SCIENCE AND TECHNOLOGY		

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).																								
2.	<p>This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.</p>																								
3.	<p>This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 30%;">Box No. I</td> <td style="width: 80%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity* of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity* of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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<input type="checkbox"/>	Box No. VIII	Certain observations on the international application																							
4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).																								

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. +41 22 740 14 35	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 5px;">Date of issuance of this report 15 May 2006 (15.05.2006)</td> </tr> <tr> <td style="padding: 5px;">Authorized officer  <div style="text-align: center; font-weight: bold; font-size: 1.2em;">Masashi Honda</div></td> </tr> <tr> <td style="padding: 5px;">Telephone No. +41 22 338 70 10</td> </tr> </table>	Date of issuance of this report 15 May 2006 (15.05.2006)	Authorized officer  <div style="text-align: center; font-weight: bold; font-size: 1.2em;">Masashi Honda</div>	Telephone No. +41 22 338 70 10
Date of issuance of this report 15 May 2006 (15.05.2006)				
Authorized officer  <div style="text-align: center; font-weight: bold; font-size: 1.2em;">Masashi Honda</div>				
Telephone No. +41 22 338 70 10				

# PATENT COOPERATION TREATY

TRANSLATION

From the  
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing  
(day/month/year)

Applicant's or agent's file reference  
**200407F-0411**

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.

**PCT/JP2004/009664**

International filing date (day/month/year)

**07.07.2004**

Priority date (day/month/year)

**09.07.2003**

International Patent Classification (IPC) or both national classification and IPC

Applicant

**NATIONAL INSTITUTE OF ADVANCED INDUSTRIAL SCIENCE AND TECHNOLOGY**

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/009664

Box No. I      Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This opinion has been established on the basis of a translation from the original language into the following language  
\_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
- a. type of material
- ☐ a sequence listing
- ☐ table(s) related to the sequence listing
- b. format of material
- ☐ in written format
- ☐ in computer readable form
- c. time of filing/furnishing
- ☐ contained in the international application as filed.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/JP2004/009664

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	1-42	YES
	Claims		NO
Inventive step (IS)	Claims	1-42	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-42	YES
	Claims		NO
2. Citations and explanations:			
(Documents)			
Document 1: WO 94/00213 A1 (Tektolit AB), 06 January 1994			
Document 2: Matsui, M. et al., "Selective Adsorption of Biopolymers on Zeolites" Chem. Eur. J., (2001), Vol. 7, pp. 1555-1560			
Document 3: Blum, Z. et al., "Removal of triton X-100 and SDS from protein solutions with zeolite Y", Acta Chem. Scand., (1990), Vol. 44, No. 5, pp. 531-532			
(Description)			
1. Novelty/inventive steps			
Document 1 describes a method for refining a hydrophobic protein using a hydrophobic zeolite. However, there is no disclosure regarding a more appropriate way of refolding this protein by contacting this zeolite.			
Document 2 describes a method for refining biopolymers by selectively adsorbing these biopolymers such as proteins or nucleic acids onto zeolites at their respective isoelectric points and eluting them under particular conditions. However, there is no disclosure regarding a more appropriate way of refolding this protein by contacting this zeolite.			
Document 3 describes a comparison of adsorption removal characteristics of the surfactants Triton X-100 (nonionic) and SDS (anionic) from male bovine blood albumin solutions using 3 kinds of zeolite (Zeolite Y, Silicalite and Mordenite) known to be hydrophobic. On this point, it is thought that correct refolding of the protein depends on the method of removal of the surfactant, but there is no disclosure in document 3 regarding the relationship between the adsorption removal characteristics and correct refolding of the protein.			
Therefore, the inventions of claims 1-42 are not disclosed in documents 1-3, and it is not found that the inventions of claims 1-42 could be easily achieved by a party skilled in the art from the disclosures in these documents.			
(Continued)			

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/009664

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

2. Industrial applicability

It is found that the inventions of claims 1-42 possess industrial applicability.